

Serial No.: 10/549,323.

Atty. Docket No. LNK-007

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REMARKSRestriction:

In the Office Action of January 30, 2007, the Examiner requested that Applicants elect one of the following inventions:

- Group I: claims 1-1-6, 16, and 17 drawn to a method of treating and/or preventing a cranial/brain trauma and/or cerebral ischemia;
and
- Group II: claims 7-15, 18, and 19, drawn to a method of treating and/or preventing a cranial/brain trauma, cerebral ischemia and/or Alzheimer's disease.

In response, Applicants provisionally elects with traverse the invention of Group I, claims 1-6, 16, and 17. However, Applicants respectfully submit that the outstanding restriction requirement is improper, in whole or in part, because under the statute, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions. In this case, the search required for the elected method of Group I overlaps with, and indeed is central to, the search required for the non-elected method of Group II. Therefore, it would not be an undue burden for the Examiner to consider claims 1-19 together in the present application. Accordingly, Applicants respectfully request that the Examiner reconsider the Restriction Requirement and specifically reconsider examining non-elected claims 7-15, 18, and 19 with the elected invention of Group I.

Election of Species:

In the outstanding Office Action, the Examiner also indicated that the application contained a number of patentably distinct species. To that end, the Examiner identified two distinct species (Species A and B), each of which contain multiple subspecies (selection of criteria (i) - (iii)). Following such instructions, Applicants are required to not only specify the particular condition to be prevented and/or treated (e.g., cerebral ischemia, cranial/brain trauma

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or Alzheimer's disease) but also its underlying cause (e.g., apoplexy, cardiac infarction or an operation), the specific array of active ingredient(s) and the specific medicinal formulation utilized (e.g., tablet vs. solution, intravenous vs. intraperitoneal, etc.). In order to be fully responsive, Applicants provisionally elect with traverse Species A, directed to a method of treating or preventing cerebral ischemia resulting from apoplexy comprising administering to a subject in need thereof a peritoneal solution containing an active ingredient comprising at least one hydrogenation product of frankincense extract, an embodiment encompassed by claims 1, 2, 4-6, 16, and 17. However, Applicants respectfully submit that such a requirement is improper, in whole or in part. Furthermore, Applicants respectively submit that the division of the present invention into innumerable distinct species is unduly restrictive and therefore constitutes an undue burden on Applicants. Accordingly, Applicants request reconsideration in view of the following remarks:

First, it is readily apparent that the Examiner has disregarded the Administrative Instructions under the PCT which expressly instruct Examiners to consider unity of invention only in relation to independent claims. Specifically:

"If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. **Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art.**" (Appendix A1, Annex B, part (c) - emphasis added)

Given that the Examiner has provided no evidence that admittedly generic claim 1 does not avoid the prior art, it is clearly erroneous to deem unity of invention to be lacking among the claims that depend therefrom. Accordingly, Applicants respectfully submit that claims 1-6, 16, and 17 must be examined together.

In addition, it is well settled that if the members of a Markush group (e.g., the alternative groupings recited in claims 1, 4, 5, etc.) are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they may be directed to independent and

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distinct inventions. Moreover, restriction among groups within a Markush claim is *per se* improper if it can be shown that the members of the Markush group share (a) a common utility and (b) a substantial structural feature essential to that utility. In this case, Applicants respectfully submits that the Markush members set forth in claims 1 *et seq.* are so few in number and interrelated that no serious burden would be imposed upon the examiner to search the entirety of the claims. However, in the event the Examiner elects to maintain the instant election of species requirement, Applicants hold in abeyance the examination of the non-elected embodiments upon an indication of allowability of the elected species pursuant to M.P.E.P. § 803.02. In particular, it is noted that "should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended [to the non-elected species]. . . The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim." M.P.E.P. § 803.02.

Finally, as noted above, it is well settled that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, in its entirety, even though it may include claims to distinct or independent inventions. In this case, it is readily apparent that the search for one species (e.g., tablet formulations, intravenous formulations) would necessarily overlap with that required for the other claimed species (e.g., solution formulations, intraperitoneal formulations). Accordingly, it appears that search and examination of all species, including the indicated subcomponents, would not constitute an undue burden on the Examiner. As there is no indication that searching multiple species would constitute an undue burden on the Examiner, the species requirement is *per se* improper.

In closing, Applicants wish to remind the Examiner that upon the allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim. In particular, once a generic claim is allowable, all of the claims drawn to species in addition to the elected species which require all the limitations of the generic claim will ordinarily be allowable over the prior art in view of the allowability of the generic claim, since the additional species will depend thereon or otherwise require all of the limitations thereof. M.P.E.P. § 806.04(d). Accordingly,

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Applicants hold in abeyance the examination of claims to the non-elected species upon an indication of allowability of one or more generic claims.

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CONCLUSION

The outstanding Office Action set a one-month shortened statutory period for response, response being due on or before March 1, 2007. In that the Petition for One-Month Extension of Time extends this deadline to on or before March 30, 2007, Applicants respectfully submit that this response is timely and no fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. 50-2101.

If the Examiner has any questions or concerns regarding this communication, he is invited to contact the undersigned.

Respectfully submitted,

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